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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,050	02/20/2002	David W. Osborne	359872001400	2420
21186	7590	02/16/2005		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/081,050	OSBORNE, DAVID W.	
	Examiner Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4,7-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4,7-22 and 25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Receipt of declaration, amendment, remarks all dated 11-29-04 is acknowledged.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-29-04 has been entered.

### ***Claim Objections***

Claims 1 and 25 are objected to because of the following informalities: Instant claims 1 and 25 recite the phrase "consists essentially of", which is improper. A proper expression would "consisting essentially of" or "comprising". Appropriate correction is required. For prosecution purposes, examiner interprets the claim language as 'comprising'.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Atrisone product sheet (from Doctor's Guide Publishing Limited, copyright 1995).

Atrisone product sheet discloses a 5% Atrisone gel, which is nothing but Dapsone gel. It is disclosed in the product sheet that Phase III clinical trials showed that 5% Atrisone gel is effective in reducing inflammatory acne lesions, reducing non-inflammatory acne lesions, reducing overall lesion count and in overall appearance. Thus, instant claims are anticipated by Atrisone product sheet.

***Claim Rejections - 35 USC § 103***

Claims 4, 7, 13, 14, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atrisone product sheet in view of US 6,060,085 ('085) or Atrisone product sheet in view of US 5,863,560 ('560).

Atrisone product sheet discussed above does not teach the claimed dapsone with dissolved and microparticulate dapsone, and also fails to teach the claimed additives.

'085 and '560 teaches topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention- both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapsone as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapsone, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapsone concentration. Both references teach dapsone in a topical composition and for the same purpose i.e., treatment of acne. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare Atrisone (of Atrisone product sheet) composition in the form of a semisolid aqueous gel having a dissolved as well as microparticulate fraction of dapsone because '085 and '560 teach that the dissolved portion of dapsone in the composition passes through intact stratum corneum in to lower third of pilosebaceous unit, whereas the microparticulate dapsone is delivered from the ruptured stratum corneum and is released for sustained and significant therapeutic benefit. Thus, a skilled artisan would have expected a multistage release of the drug, Atrisone, depending on the intact stratum corneum and provides an effective treatment to acne. Accordingly,

optimizing the amount of dapsone so as to achieve the desired reduction in acne would have been within the scope of a skilled artisan.

Claims 8-12 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atrisone and US 6,060,085 or Atrisone and US 5,863,560 ('560) in view of US 6,200,964 to Singleton et al.

Instant claims are directed to different formulations of dapsone, which are not taught by any of Atrisone, '085 or '560.

'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the compositions containing dapsone (Atrisone) containing dissolved and microparticulate fractions, in the form of a spray, lotion or a cream or an ointment because '964 teaches acne preparations can be in the above forms and a skilled artisan would still be able to obtain the effect of dapsone in treating acne so as to reduce the number of inflammatory or non-inflammatory lesions.

#### *Response to Arguments*

Applicant's arguments and the declaration with respect to claims 1, 4, 7-22 and 25 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
February 14, 2005